QA Information Notice for Health Products

IN Nº 2025-04 **Version 1- 2025-07-02**	**Precautionary measures in procuring Indoor Residual Spraying (IRS) product, Revival 100 CS supplied by Tagros Chemicals India Pvt. Ltd**

Addressees

- Through Health Product Management (HPM) Specialists, all Principal Recipients (PR) reporting procurement of the impacted product financed by the Global Fund.
- All procurers, buyers reporting procurement of the impacted product financed by the Global Fund.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this QA Information Notice to provide precautionary measures following out-of-specifications observed on IRS product, Revival 100 Capsule Suspension (CS), commercialized by Tagros Chemicals India Pvt. Ltd.

This QA Information Notice is for internal and external dissemination and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name & Address of the Manufacturer	Tagros Chemicals India Pvt. Ltd A-4/1 & A-4/2, SIPCOT Industrial Complex, Pachayankuppam, Cuddalore-607 005 Tamil Nadu, India
Commercial / Brand Name(s)	Revival 100 CS (Lambda-Cyhalothrin 10% capsule suspension)
Formulation	Capsule suspension
Batch(es)	All
Manufacturing Date	All

Background

In May 2025, the Global Fund Supply Operations (SO) – QA & Compliance team received quality analysis reports from a contracted ISO 17025 accredited Laboratory for one batch of Revival 100 CS manufactured by Tagros Chemicals India Pvt. Ltd identifying out of specification results. This was during pre-shipment quality control testing as per the requirement of the Quality Assurance Policy for Vector Control Products and Related Equipment https://www.theglobalfund.org/en/sourcing-management/quality-assurance/vector-control-products/. The supplier has been informed of the out-of-specification results, and a root cause analysis is being performed to identify any potential necessary corrective and preventive actions to be implemented.

Nature of defect(s)

Details of the defect or problem	Higher release rate of lambda-cyhalothrin before and after storage.
Is there any evidence or suspicion of a risk to users/others	The product is designed to protect the active ingredient from immediate release. This ensures a prolonged effect on treated surfaces. A higher release rate may reduce long-term residual action of the product on the sprayed walls hence reduce mosquito mortality.
Extent of the problem (e.g. No. of batches)	Only one batch, ALCS24V008, procured for Zimbabwe, was tested and found to be defective, but other batches could be impacted.
Extent of distribution of the product / batch(es)	No known countries where the product has been distributed. However, procurement and distribution of impacted products directly through Principal Recipients cannot be excluded.
Number of users/others potentially impacted	No directly impacted users known or reported.

Next Steps/ Recommendations

Based on the information available to date and until further notice, the following actions are recommended by the Global Fund Quality Assurance & Compliance team as precautionary measures.

- **New orders**

1. Halt any new orders or procurements of the Revival 100 CS product.

2. Consider alternative procurement of:

    a) Interchangeable/Substitutable product from a different supplier.

    b) Different IRS product as per the National Malaria program guidelines.

- **Already procured products (or procurement underway)**

Where pre-shipment quality control testing did not identify any nonconformity, supply of the procured batch(es) should continue.

However, it is requested to segregate from other products, quarantine and dispose of, as per agreed procedures with the supplier, any product batches with issues related to higher release rate of lambda-cyhalothrin before and after storage.

Any of these product nonconformities should be reported to the Global Fund through the respective Country Team/HPM Specialist.

Exceptions to accommodate programmatic risks are to be submitted, on case-by-case basis, to the respective Country Team/HPM Specialist to be forwarded to the Quality Assurance and Compliance team for assessment and guidance.

Users/Others

Users who have experienced any adverse reactions or quality problems with the use of the impacted products may report this to the relevant Regulatory Authorities, manufacturer and the Global Fund Country Team /HPM Specialist

Transmission of QA Information Notice

This QA Information Notice needs to be passed on to all those who need to be aware within your organization and/or to any organization where the potentially impacted products have been transferred. Please maintain awareness of this QA Information Notice and resulting actions for an appropriate period to ensure effectiveness of the corrective action(s).

Validity

The QA Information Notice will be valid from date of publication on the Global Fund Information Notice webpage https://www.theglobalfund.org/en/sourcing-management/quality-assurance/information-notice/ until it is either removed or superseded by a new notice.

Contacts

This QA Information Notice does not require specific written response from PR and procurers to the Global Fund.

PRs and procurers should copy the Global Fund's Country Team/HPM Specialist on correspondences regarding the matter for follow-up.

Please direct any questions about this matter to the technical contact listed below.

Organisation	**Name / Function**	**E-mail address**
Global Fund	Respective Country Team/HPM Specialist for the portfolio	
Global Fund	Anne-Sophie Briand, Senior Specialist, Vector Control Products, Direct Sourcing	Anne-Sophie.Briand@theglobalfund.org
Global Fund	Stephen Kimatu, Specialist-Vector Control Quality Assurance, Quality Assurance & Compliance	Stephen.Kimatu@theglobalfund.org